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DECEMBER 7, 2020 BY RONNIE

Health Canada Refuses To Answer Questions About Indemnification For Vaccines

Government of Canada / Gouvernement du Canada

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Drug and vaccine authorizations for COVID-19: List of authorized drugs and expanded indications

Overview | List of applications received | List of authorized drugs

Date published: 2020-11-20

Drugs that have been authorized by Health Canada for use in relation to the COVID-19 pandemic are listed here.

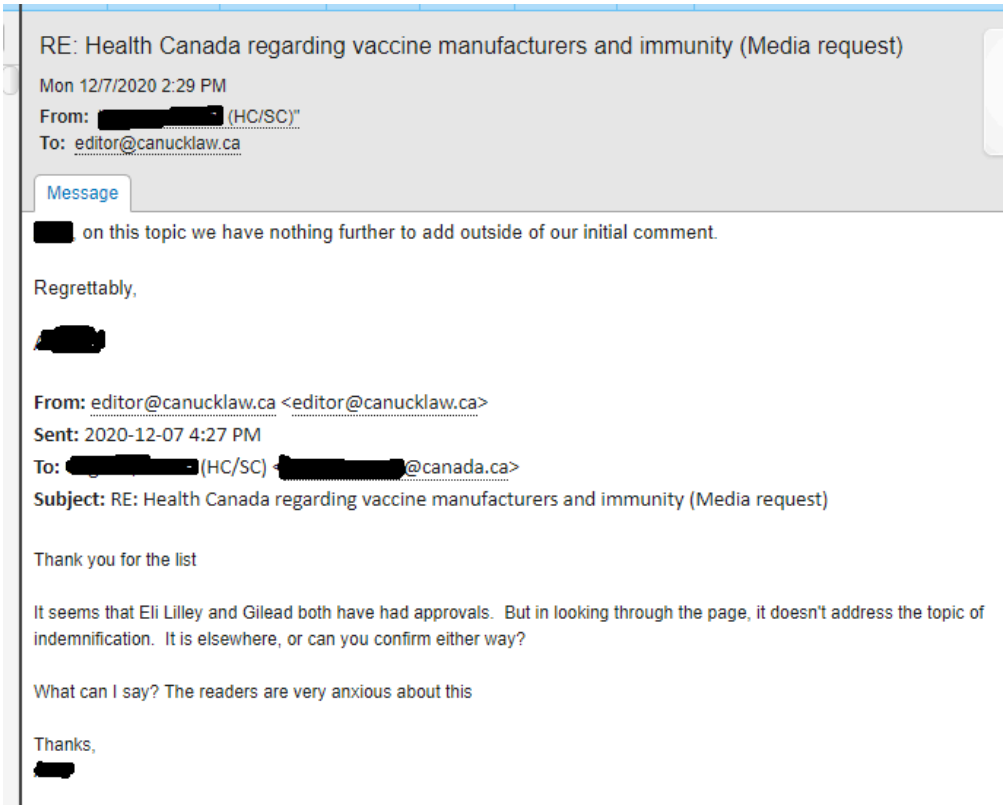
In the list below, the entry for each authorized drug includes the:

- authorization holder

Applicant	Medicinal ingredient(s)	Therapeutic area	application was received	Outcome of application	Date of decision/out
AstraZeneca Canada Inc.	Adenovirus vaccine vector (ChAdOx1)	Vaccines, for human use	2020-10-01	Pending	n/a
Eli Lilly Canada Inc.	Bamlanivimab (LY-CoV555)	Immune sera and immunoglobulins, for human use	2020-10-12	Authorized (with terms and conditions)	2020-11-20
Gilead Sciences Canada Inc.	Remdesivir	Antivirals for systemic use, for human use	2020-06-19	Authorized (with conditions)	2020-07-27
Janssen Inc	JNJ-78436735/Ad26.COV2.S	Vaccines, for human use	2020-11-30	Pending	n/a
Moderna Therapeutics Inc.	mRNA-1273 vaccine	Vaccines, for human use	2020-10-12	Pending	n/a
Pfizer Canada ULC/BioNTech SE	mRNA vaccine BNT162b2	Vaccines, for human use	2020-10-09	Pending	n/a

The public is understandably anxious about whether vaccine manufacturers will be indemnified (legally immune), for the products they sell. It's a valid question, from a patient perspective, and as a taxpayer.

Email Exchange With Health Canada



RE: Health Canada regarding vaccine manufacturers and immunity (Media request)

Mon 12/7/2020 2:29 PM

From: [redacted] (HC/SC)"

To: editor@canucklaw.ca

Message

[redacted] on this topic we have nothing further to add outside of our initial comment.

Regrettably,

[redacted]

From: editor@canucklaw.ca <editor@canucklaw.ca>

Sent: 2020-12-07 4:27 PM

To: [redacted] (HC/SC) <[redacted]@canada.ca>

Subject: RE: Health Canada regarding vaccine manufacturers and immunity (Media request)

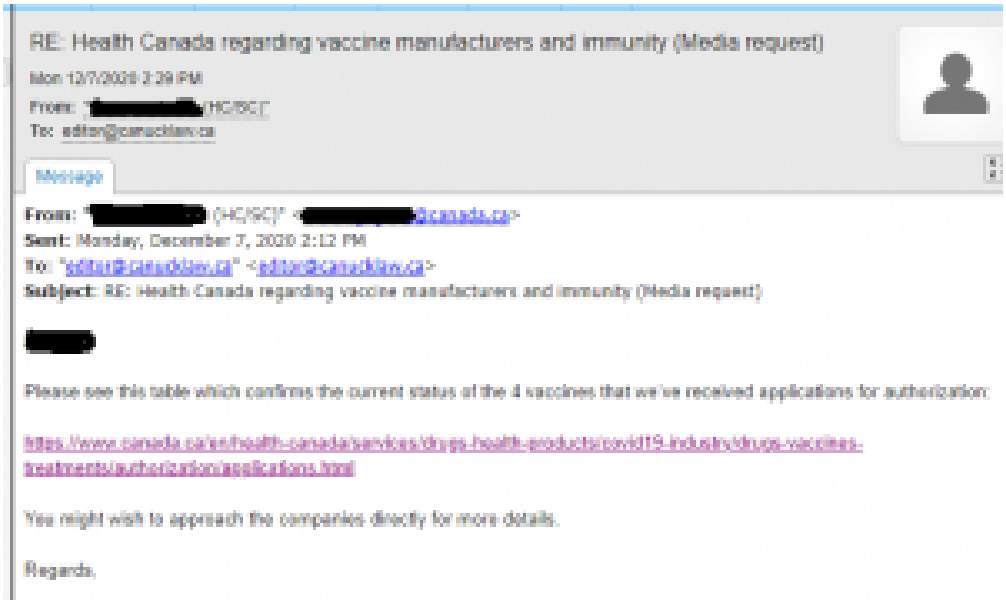
Thank you for the list

It seems that Eli Lilley and Gilead both have had approvals. But in looking through the page, it doesn't address the topic of indemnification. It is elsewhere, or can you confirm either way?

What can I say? The readers are very anxious about this

Thanks,

[redacted]



RE: Health Canada regarding vaccine manufacturers and immunity (Media request)

Mon 12/7/2020 2:29 PM

From: "[redacted]/HC/SC)"

To: editor@canucklaw.ca

Message

From: "[redacted] (HC/SC)" <[redacted]@canada.ca>

Sent: Monday, December 7, 2020 2:12 PM

To: "editor@canucklaw.ca" <editor@canucklaw.ca>

Subject: RE: Health Canada regarding vaccine manufacturers and immunity (Media request)

[redacted]

Please see this table which confirms the current status of the 4 vaccines that we've received applications for authorization:

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/applications.html

You might wish to approach the companies directly for more details.

Regards,

RE: Health Canada regarding vaccine manufacturers and immunity (Media request)

Mon 12/7/2020 2:29 PM

From: [redacted] (HC/SC)

To: editor@canucklaw.ca

Message

From: [redacted] (HC/SC) <[redacted]@canada.ca>

Sent: Monday, December 7, 2020 1:45 PM

To: "editor@canucklaw.ca" <editor@canucklaw.ca>

Subject: Health Canada regarding vaccine manufacturers and immunity

Hi [redacted]

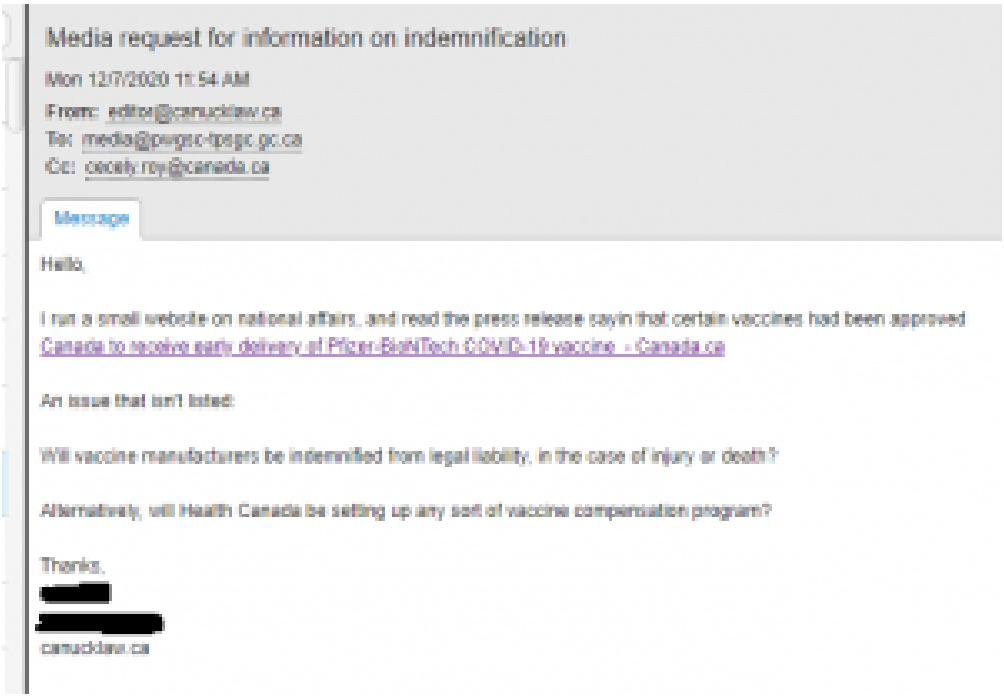
Please see our response below:

If you could please confirm receipt.

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and effectiveness of the vaccine and monitor and communicate any potential adverse events following immunization. Health Canada will not hesitate to take action if a safety issue is identified.

At this time, we cannot disclose details of specific agreements in an effort to protect our negotiating position and commercially sensitive pricing information, as well as to respect confidentiality clauses in our vaccine agreements.



Media request for information on indemnification

Mon 12/7/2020 11:54 AM

From: editor@canucklaw.ca

To: media@pwgsc-tpsgc.gc.ca

Cc: cecely.roy@canada.ca

Message

Hello,

I run a small website on national affairs, and read the press release sayin that certain vaccines had been approved Canada to receive early delivery of Pfizer-BioNTech COVID-19 vaccine - Canada.ca

An issue that isn't listed:

Will vaccine manufacturers be indemnified from legal liability, in the case of injury or death?

Alternatively, will Health Canada be setting up any sort of vaccine compensation program?

Thanks,

[redacted]

[redacted]

canucklaw.ca

Health Canada was contact specifically about the indemnification of vaccine manufacturers. Above are the responses. However, it's a bit misleading to say that they can't release information due to ongoing negotiating. Health Canada wouldn't even discuss indemnification for Eli Lilly Canada and Gilead Sciences Canada. Both had been settled long ago.

Health Canada And Vaccine Regulation

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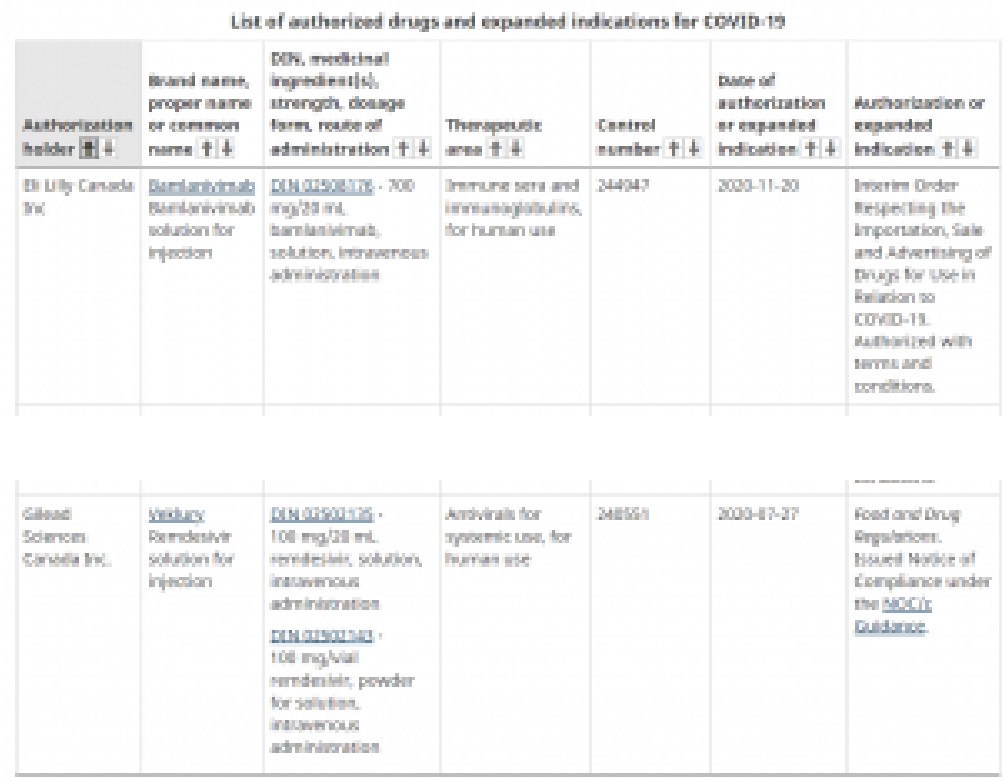
Regulating vaccines for human use in Canada

Learn more about Vaccines and treatments for COVID-19.

Vaccination is one of the world's greatest public health achievements. For over 50 years, vaccines have helped prevent and control the spread of deadly diseases and saved the lives of millions of infants, children and adults. For example, there are vaccines for:

- epidemics, such as Ebola
- childhood diseases and debilitating diseases, such as polio
- diseases, such as Yellow Fever, that are common in some travel destinations



List of authorized drugs and expanded indications for COVID-19

Authorization holder	Brand name, proper name or common name	DIN, medicinal ingredient(s), strength, dosage form, route of administration	Therapeutic area	Control number	Date of authorization or expanded indication	Authorization or expanded indication
Eli Lilly Canada Inc	Bamlanivimab Bamlanivimab solution for injection	DIN 02508176 - 700 mg/20 mL bamlanivimab, solution, intravenous administration	Immune sera and immunoglobulins, for human use	244947	2020-11-20	Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. Authorized with terms and conditions.
Gilead Sciences Canada Inc.	Veklury Remdesivir solution for injection	DIN 02503126 - 100 mg/20 mL remdesivir, solution, intravenous administration DIN 02503340 - 100 mg/vial remdesivir, powder for solution, intravenous administration	Antivirals for systemic use, for human use	248551	2020-07-27	Food and Drug Regulations. Issued Notice of Compliance under the MOC(s) Guidance.

Vaccination is one of the world's greatest public health achievements. For over 50 years, vaccines have helped prevent and control the spread of deadly diseases and saved the lives of millions of infants, children and adults. For example, there are vaccines for:

-epidemics, such as Ebola
-childhood diseases and debilitating diseases, such as polio
-diseases, such as Yellow Fever, that are common in some travel destinations
-influenza strains that change every year

> -preventing or treating cancer
> Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. This means that they are given to large numbers of healthy people.

> This is why regulating the safety, efficacy and quality of vaccines is of particular importance. There are also reporting systems in place to monitor vaccine safety.

https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/activities/fact-sheets/regulation-vaccines-human-canada.html

> Emergency access to vaccines
> In some cases, such as public health emergencies like flu pandemics, special authorizations are used to give emergency access to a vaccine. For example, ***Health Canada issued an Interim Order in 2009 for the H1N1 pandemic vaccine. The vaccine was developed to protect against the H1N1 pandemic virus***. The vaccine contained an inactivated (non-live) version of the H1N1 virus strain recommended by WHO for the manufacture of vaccines during the 2009 flu pandemic.

Worth addressing: in that 2009 Interim Order to approve vaccines for H1N1, Health Canada allowed drugs made by GlaxoSmithKline, (GSK), onto the market that hadn't been fully tested. GSK was indemnified by the Government. Would it happen here?

Why is it so hard to get a straight answer with this case? Will they be indemnified or not?

CANADA, CRIMINAL, GLOBALISM, HEALTH, NGO/CS, UN/WHO, VACCINES